CENTER FOR DRUG ... RESEARCH

Individual Safety Report

3374055-X-00-01

McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15-93

Mfr report #

IND/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
unknown In confidence	29 yrs or Date of birth:	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. (X) Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr:)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
unknown	10/05/99

5. Describe event or problem

Lit report (J Toxicol Clin Toxicol 1999;37(5):604) of acute LIVER FAILURE associated w/oral halothane ingestion. According to report, 29 yo male w/hx of bipolar disorder & alcoholic liver dx presented to ED 5 days after hosting a party where participants were "huffing halothane". Pt denies using halothane personally. The next AM, pt took morning dose of gabapentin with approx 2.5 oz of halothane thinking it was water. Realizing it was halothane, pt immediately began to vomit & had intractable emesis for 5 days. In ED, pt's temp was 103.7,HR=119,RR=18 &BP=155/70. PE revealed obese male in mild distress from emesis & apparent abdominal discomfort. Pt's abdomen was non-distended w/out hepatosplenomegaly but was tender to palpitation over epigastrium. AST & ALT were increased & chest X-ray showed RML infiltrate. Pt d/c'd on po quinolone. Three days later, pt presented for a 2nd time w/ increased NAUSEA AND VOMITING & ABDOMINAL PAIN. Pt admitted using an unspecified dose of APAP for fever & discomfort. Lab results showed LIVER FUNCTION TESTS (See Sect 87)

6. Relevant tests/laboratory data, including dates

In ER: T=103.7, HR=119, RR=18, BP=155/70, ALT=214 IU/L, AST=201 IU/L, CXR showed R middle lobe infiltrate; 3 days later: AST=2760, ALT=2347, PT=18.8 sec, APTT=41.4 sec, toxicology (+) for cannabinoids, APAP level=18 mcg/ml; (See Sect C10)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

bipolar disorder, alcoholic liver disease; denies ETOH use in past 5 years; (Sect B5 cont) ABNORMAL, & PROTHROMBIN & THROMBOPLASTIN INCREASED. APAP level was 18 mcg/ml. Tox screens were (+) for cannabinoids. Pt admitted for acute liver failure thought to be secondary to halothane ingestion. Pt left AMA on day 2.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unknown acetaminophen product
#2 halothane

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 unknown dates or duration
#2 2.5 oz, once, po	#2 unknown date; once

4. Diagnosis for use (indication)

#1 fever and discomfort
#2 accidental ingestion

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2 unknown	#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

gabapentin

(Sect B6 cont) hospital day 2: AST=752, ALT=1366

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7820

3. Report source (check all that apply)

( ) foreign
( ) study
(X) literature
( ) consumer
( ) health professional
(X) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr)	5.
10/05/99	(A) NDA # 19-872
6. If IND, protocol #	IND #
	PLA #
	pre-1938 ( ) Yes
	OTC product (X) Yes

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)

LIVER FAILURE NAUSEA VOMIT
PAIN ABDOMINAL LIVER FUNC ABNO
PROTHROMBIN INC THROMBOPLASTIN

9. Mfr. report number

1248432A

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	health prof.	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.